**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**
**NEWARK VICINAGE**

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| **UNITED STATES OF AMERICA, STATE OF NEW JERSEY, STATE OF _____ EX REL. JAMIE ERFLE,** | : | **CIVIL ACTION NO. _____** |
| **Plaintiffs** | : | ***FILED IN CAMERA AND UNDER SEAL*** |
| **v.** | : | ***JURY TRIAL DEMANDED*** |
| **SANOFI-AVENTIS, a business entity form unknown; SANOFI-AVENTIS U.S., LLC: a corporation; AVENTIS PHARMACEUTICALS, INC.: a corporation; AVENTIS, S.A., a business entity form unknown; AVENTIS, INC., a corporation; SANOFI-SYNTHELABO, a business entity form unknown; HOECHST MARION ROUSSELL, INC., a corporation; RHONE POULANC, S.A., a business entity form unknown;** | : | |
| **Defendant(s)** | : | |

**COMPLAINT FOR DAMAGES AND OTHER RELIEF UNDER THE *QUI TAM* PROVISIONS OF THE FEDERAL FALSE CLAIMS ACT AND SIMILAR STATE PROVISION(S)**

## I. JURISDICTION AND VENUE

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the State of New Jersey, arising from Defendants Sanofi-Aventis, et al's conduct in conspiring to cause false claims to be presented under the Federal Medicare, Medicaid, and CHAMPUS Programs.

2. Medicare is a federally funded health insurance program primarily for the elderly. Medicaid is a state and federal assistance program to provide payment of medical expenses for low-income patients. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") is a program of medical insurance benefits provided by the federal government to individuals with family affiliations to the military services.

3. These *qui tam* claims arise under the provisions of the False Claims Act, 31 U.S.C. § 3729 *et seq.* This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 3732, which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

4. Personal jurisdiction and venue for this action are predicated on 31 U.S.C. § 3732(a), which provides that "any action brought under § 3730 may be brought in any judicial district in which the defendant, or in the case of multiple defendants, any one defendant, can be found, resides, transacts business or in which any act proscribed by § 3729 occurred." Defendant Sanofi-Aventis transacts substantial business in the State of New Jersey.

5. This Court also has supplemental jurisdiction over the state law *qui tam* claims pursuant to 28 U.S.C. § 1367, which provides that "in any civil action of which the district courts have original jurisdiction, the district courts shall have supplemental jurisdiction over all other

claims that are so related to claims in action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution."

6. Under the False Claims Act, this Complaint is to be filed *in camera* and remain under seal for a period of at least 60 days and shall not be served on the defendant(s) until the Court so orders. The government may elect to intervene and proceed with the action within 60 days after it receives both the Complaint and the material evidence and information.

## II. PARTIES

7. *Qui tam* Plaintiff Jamie Erfle ("Erfle" or "Relator") is a citizen and resident of the state of Pennsylvania.

8. Erfle is a former employee of Sanofi-Aventis. She has personal knowledge of Sanofi Aventis's conduct and its conspiracy with doctors as set forth herein.

9. As required under the False Claims Act, Erfle has provided to the Attorney General of the United States and the United States Attorney for the District of New Jersey simultaneously with the filing of this Complaint, a statement of all material evidence and information related to the Complaint. This disclosure statement supports the existence of false claims by Sanofi-Aventis and possibly others in the Medicare, Medicaid and CHAMPUS programs.

10. Defendants Sanofi-Aventis; Sanofi-Aventis U.S., LLC; Aventis Pharmaceuticals, Inc.; Aventis, Inc.; Aventis, S.A.; Sanofi-Synthelabo; Hoechst Marion Rousell, Inc.; and Rhone Poulanc, S.A. designed, researched, developed, formulated, applied for Food and Drug Administration ("FDA") approval to manufacture and sell, manufactured, tested, conducted and engaged in clinical studies regarding, advertised, promoted, labeled, packaged, marketed, sold,

and distributed the ketolide antibiotic "telithromycin," known under the brand name "Ketek®."

11. In or about 1999, Aventis, Inc. was formed as a result of a merger between Rhone Poulanc, S.A., a French corporation, and Hoechst Marion Roussel, a German corporation, with a principal place of business located at all times relevant to this action in Kansas City, Missouri.

12. Aventis Pharmaceutical, Inc. is and was at all relevant times to this action a corporation formed under the laws of the State of Delaware with its principal place of business located in Bridgewater, New Jersey.

13. Aventis, Inc. was and is a corporation and a wholly-owned U.S. subsidiary of the pharmaceutical manufacturer Aventis, S.A., a business entity located in Strasbourg, France.

14. Aventis, Inc. was and is a corporation formed under the laws of the Commonwealth of Pennsylvania, with its principal place of business located in Bridgewater, New Jersey.

15. On or about December 31, 2004, Aventis, S.A. of Strasbourg, France merged its operations with the pharmaceutical manufacturer Sanofi-Synthelabo (also known as "sanofi-synthelabo"), a business entity formed under the laws of France in 1994 as a type of limited liability company known as a "societe anonyme." At all times relevant to this action, Sanofi Synthelabo also was identified as "Sanofi Synthelabo" and/or "sanofi synthelabo."

16. The merger of Aventis, S.A. with Sanofi-Synthelabo formed the business entity Sanofi-Aventis (also known as "sanofi-aventis") with a registered office formerly and/or currently located at 174 avenue de France, 75013 Paris, France.

17. Sanofi-Aventis is the parent of a consolidated group of business entities, form unknown, that inclues the U.S. corporations Aventis, Inc. and Aventis Pharmaceuticals, Inc. As

such, Defendants are liable for the actions and conduct of the other Defendants as either successors and/or predecessors in interest to the other Defendants.

18. As a result of the merger of Aventis, S.A. and Sanofi-Synthelabo, Aventis, Inc. is and was at all times relevant to this action a wholly-owned subsidiary of Sanofi-Aventis, with its principal place of business formerly and/or presently located at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey. As such, Defendants are liable for the actions and conduct of the other Defendants as either successors and/or predecessors in interest to the other Defendants.

19. As a result of the merger of Aventis, S.A. and Sanofi-Synthelabo, Aventis Pharmaceuticals, Inc. is and was at all times relevant to this action a wholly-owned subsidiary of Sanofi-Aventis, with its principal place of business formerly and/or presently located in Bridgewater, New Jersey. As such, Defendants are liable for the actions and conduct of the other Defendants as either successors and/or predecessors in interest to the other Defendants.

20. Sanofi-Aventis U.S., LLC is a wholly-owned subsidiary of Sanofi-Aventis, with its principal place of business located in Bridgewater, New Jersey.

21. At all times relevant to this action, Sanofi-Aventis, by or through one or both of its wholly-owned subsidiaries Aventis, Inc.; Aventis Pharmaceuticals, Inc.; and/or Sanofi-Aventis U.S., LLC, manufactured, marketed, applied for FDA approval of the manufacture and sale of, and sold Ketek® throughout the United States.

22. Sanofi-Aventis, by or through one or both of its wholly-owned subsidiaries Aventis, Inc.; Aventis Pharmaceuticals, Inc.; and/or Sanofi-Aventis U.S., LLC, at all times relevant to this action, manufactured and/or manufactures Ketek® at facilities formerly and

presently located in Kansas City and St. Louis, Missouri.

23. Sanofi-Aventis; Aventis, S.A.; Aventis, Inc.; Aventis Pharmaceuticals, Inc.; and Sanofi-Aventis U.S., LLC, were and are at all times relevant to this action, the manufacturers of the antibiotic pharmaceutical known as "Ketek®." The Complaint hereafter refers to these Defendants collectively as "Defendants" or "Sanofi-Aventis."

24. At all times relevant to this action, the manufacturers of Ketek®, together and in concert with each other, were engaged in the design, development, manufacture, testing, application for FDA approval for the manufacture and sale, packaging, promotion, marketing, distribution, labeling, advertisement, and sale of Ketek® to millions of American consumers.

25. There existed at all times relevant to this action a unity of interest in ownership between and among the Ketek® manufacturer Defendants, such that any independence from, and/or separation between and among the Defendants has ceased and/or never existed, in that Defendants, and each of them, are the alter-egos of one another and exerted direction and control over each other. Adherence to the fiction of a separate and independent existence among the Defendants, as separate entities distinct from one another would permit an abuse of the corporate privilege, sanction a fraud upon the United States, the State of New Jersey, and upon millions of other consumers of Ketek®, and would promote injustice. The Defendants, and each of them, encouraged, directed, condoned and ratified the negligent, willful, intentional, and wrongful acts, omissions, and conduct of each and all of the Defendants herein as regards to the application for, and clinical trials in obtaining, FDA approval for the manufacture and sale of Ketek.®

## III. FACTUAL ALLEGATIONS

### A. Ketek Background Facts

### 1. Ketek Manufacturers' First Attempt to Obtain FDA Approval

26. On or about March 20, 1998, Defendants, by and through their officers, directors, agents, servants, employees, and representatives, filed an Investigational New Drug Application (IND) with the United States Food and Drug Administration (FDA) for approval of the pharmaceutical drug, Ketek®. The Ketek® IND was numbered 55,283 and related to the development of what was claimed to be the first semi-synthetic abtibiotic.

27. Defendants represented that Ketek®'s unique biochemical composition would defeat resistant strains of bacteria that cause ailments such as sinusitis, bronchitis, and pneumonia.

28. Relator is informed and believes, and thereupon alleges, that Defendants manufactured, marketed, advertised, and sold Ketek® for the primary purpose of reaping annual revenues in excess of $1 billion dollars and thus concealed and misrepresented to the FDA the true and accurate facts and information required to be submitted in filing the Ketek® IND.

29. Defendants filed a New Drug Application (NDA) for Ketek® wih the FDA on or about March 1, 2000. The NDA was identified as NDA 21-144 and sought FDA approval to manufacture, package, label, market, and sell Ketek® in the United States. Ketek® was approved for sale in Europe in 2001, prior to the FDA's approval of Ketek® for sales in the United States.

30. Defendants' NDA 21-144 stated that Ketek® was intended for treatment of infectious diseases caused by susceptible strains of designated microorganisms in acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and community acquired pneumonia for patients 18 years and older.

31. Relator is informed and believes, and thereupon alleges, that Defendants concealed from and misrepresented to the FDA the true and accurate information known by Defendants regarding the true serious health and safety risks associated with Ketek®, in filing Defendants' NDA.

32. The FDA convened a meeting of the Anti-Infective Drugs Advisory Committee (AIDAC) on or about April 26, 2001, to review Defendants' NDA 21-144 and consider whether Ketek® was efficacious and adequately and safely treated acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, community acquired pneumonia, and tonsillopharyngitis in light of the known risks of cardiac and hepatic toxicity, and visual disturbances associated with Ketek®.

33. The Defendant manufacturers of Ketek® presented data and information to the Committee regarding the safety and efficacy of Ketek®. The AIDAC expressed concern regarding hepatic and other serious adverse events connected with the use of Ketek®. The AIDAC recommended that the Ketek® manufacturers be required to conduct a large clinical study and present the clinical data to the AIDAC for further consideration of approval of Ketek® for the indicated uses set forth in NDA 21-144.

34. NDA 21-144 was thereafter considered by the FDA's Review Division. On June 1, 2001, the FDA issued an "approvable lettter" to the Ketek® manufacturers regarding the indicated uses for acute bachterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and community acquired pneumonia. A no-approval letter was issued as to Ketek®'s use for tonsillopharyngitis.

35. Consistent with the AIDAC's recommendation, the FDA's June 1, 2001

"approvable letter" requested Ketek® manufacturers to conduct a large-scale safety study of patients using Ketek® in usual care settings, and stated as follows:

> Recruitment of patients with renal and/or hepatic impairment is encouraged. This study should include the monitoring and analysis of all adverse events, with particular attention to hepatic, visual, cardiovascular, and vasculitic adverse events.

36. In August 2001, financial analysts forecast that Aventis, Inc., as the manufacturer of Ketek®, would realize billions of dollars in Ketek® sales by the year 2005, and that delayed FDA approval of the drug would have a significant negative impact on Defendants' projected profits.

### 2. Defendants' Second Attempt to Obtain FDA Approval of Ketek® – Study 3014

37. On October 17, 2001, the Ketek® manufacturer Defendants submitted a study protocol known as "Study 3014" to the FDA, which was intended to provide the additional safety data requested in the FDA's June 1, 2001 "approvable letter." Study 3014 was formally titled "*Randomized, Open-Label, Multicenter Trial of the Safety and Effectiveness of Oral Telithromycin (Ketek®) and Amoxicillin/Clavulanic Adic (Augmentin®) in Outpatients With Respiratory Tract Infections in Usual Care Settings, HMR3647A/3014, Telithromycin.*"

38. Defendants retained and hired as their agent and representative Pharmaceutical Product Development, Inc. (PPDI) to conduct, coordinate, organize, manage, monitor, oversee, and supervise the clinical trial described in Study 3014. PPDI was to provide regular periodic progress reports to the Ketek® manufacturers regarding the progress of the study and whether the required procedures and protocols were adhered to and being followed. Defendants and PPDI retained and hired The Copernicus Group, Inc. ("Copernicus") as the Institutional Review Board

(IRB) for Study 3014. Study 3014 was launched in October 2001.

39. Copernicus was hired and required to conduct oversight reviews of all Study 3014 study sites, undertake procedures, policies, and protocols to protect the health and welfare of patients enrolled in the study, and to ensure the integrity and accuracy of the study results.

40. Relator is informed and believes, and thereupon alleges, that PPDI and Defendants were required to enroll no fewer than 24,000 patients to complete Study 3014. Defendants originally represented to the FDA that approximately eight months would be required to enroll the minimum number of participants. Contrary to the required eight-month study period, Defendants concluded Study 3014 after only four months.

41. Relator is informed and believes, and thereupon alleges, that PPDI, in acting as the principal and/or agent of Defendants, and acting within the course and scope of its principal and agent relationships with Defendants, hired, engaged, retained, and financially compensated physicians to conduct and oversee the proper procedures and protocols to ensure the integrity and accuracy of the results of Study 3014. Relator is informed and believes, and thereupon alleges, that these physicians/principal study investigators produced and submitted false and inaccurate data and results regarding Study 3014.

42. Defendants had knowledge of and were aware from October 2001 through the end date of Study 3014 that the physician study investigators at Study 3014 study sites violated study protocols and procedures, provided and submitted to the FDA inaccurate and fraudulent data regarding the study subjects and the results and data from Study 3014. Defendants took no action to remedy the reported study protocol violations and inaccurate and false study data, and instead encouraged, directed, ratified, condoned, and promoted the protocol violations and

submission of false study data to the FDA.

43. The FDA's approval of the manufacture and sale of Ketek® in the United States was significantly and principally based upon the false and inaccurate data and study results submitted by Defendants regarding Study 3014.

### 3. Defendants Submit Inaccurate and False Results of Study 3014

44. Defendants submitted an amended NDA 21-144 to the FDA on July 24, 2002 to obtain FDA approval for the sale of Ketek® in the U.S. market. Defendants represented to the FDA that the contents and data contained in the amended NDA 21-144 were the true and accurate results of Study 3014. The amended NDA 21-144 indicated that the data reported as having been obtained from Study 3014 established that Ketek® was safe and efficacious, and carried no serious risk of harm for patients who consumer Ketek®.

45. Defendants, through their officers, directors, supervisors, agents, representatives, and employees, knew and/or should have known, at the time they submitted the data and results of Study 3014 to the FDA, that the data and results regarding the safety and efficacy of Ketek® were false and inaccurate and failed to disclose the true and accurate nature and extent of the serious risks of harm Defendants knew or should have known were associated with the ingestion of Ketek®. Defendants knew or should have known at the time they submitted the false and inaccurate Study 3014 results and data that there in fact existed a serious risk of harm to the health and well being of persons taking Ketek®.

46. Defendants failed to disclose to the FDA the true facts regarding the study protocol violations and breaches of duty committed during Study 3014 by Defendants' agents. By way of example, Covance, Inc., with facilities in Indianapolis, Indiana, was the laboratory to

which the principal study investigator Dr. Maria Anne Kirkman-Campbell submitted blood samples obtained in Study 3014 for analysis. Relator is informed and believes that the blood samples analyzed by Covance were not properly labeled, were contaminated and tainted, and not actually drawn from the study patients as indicated on the blood sample. Covance mishandled the blood samples and failed to follow strict study protocols and guidelines in testing and analyzing the blood samples received from the Kirkman-Campbell study site. These breaches of protocol resulted in false and inaccurate data and study results regarding the safety of Ketek® being obtained, recorded, reported, and ultimately submitted to the FDA to obtain official approval for Defendants' manufacture and sale of Ketek® in the U.S.

47. On or about October 24, 2002, the FDA conducted what is known as a Bioresearch Monitoring Program ("BMP") inspection of the "highest enrolling" investigational site for Study 3014. The site enrolled 407 patients under the care of investigator Dr. Maria-Anne Kirkman Campbell, M.D.

48. The FDA inspectors identified numerous protocol violations, and negligent and fraudulent practices at the Kirkman-Campbell site, including enrolling fictitious subjects; reporting data on patients who never participated in or completed the study; using blood samples drawn and analyzed from persons other than the patients enrolled in the study; and inaccurately and falsely documenting results and other study data.

49. After FDA inspection of the Kirkman-Campbell study site, the FDA's Office of Criminal Investigations ("OCI") was informed of numerous regulatory, as well as possible criminal, violations by persons involved in the enrollment and treatment of Study 3014 patients at the Kirkman-Campbell site. The FDA also discovered similar study protocol violations at

other Study 3014 sites. Relator is informed and believes that Dr. Carl K. Lang, M.D. enrolled the second largest group of subjects in Study 3014. An FDA inspection of the Lang site found that Lang failed to follow the study plan and consistently failed to report adverse drug reactions. The study data and results from the Lang study site were reported to the FDA as true and accurate data, and were relied upon by the FDA in providing approval for Defendants' manufacture and sale of Ketek in the U.S.

50. Relator is informed and believes that Dr. Egisto Salerno, M.D., was the principal investigator at the Study site that enrolled the third largest group in Study 3014. Relator is informed and believes that Dr. Salerno was placed on probation with the Board of Professional Medical Conduct for the State of New York and the Board of Medical Quality Assurance for the State of California for committing malpractice and for conduct that constituted various infractions of medical regulations and protocols. PPDI on behalf of Defendants employed Dr. Salerno to participate in Study 3014 with knowledge of the disciplinary action involving his gross and repeated negligence and failure to maintain true and accurate medical records. Relator is informed and believes that, while on probation for these violations, Dr. Salerno oversaw and was involved in directing and investigating the third largest group of patients (214 patients) involved in Study 3014. Relator is informed and believes that the State of California has revoked Dr. Salerno's medical license and that he is barred from practicing medicine in the State of New York.

51. Relator is informed and believes that Dr. Jeffrey L. McLeod, M.D., failed to obtain informed consent from at least seven patients who participated in Study 3014 at his study site. Dr. McLeod also submitted informed consent documents signed on dates after the

Completion of Study 3014 for six patients enrolled at his study site. Dr. McLeod also submitted signed written informed consent documents with 17 backdated patient signatures. Dr. McLeod also submitted to the FDA 13 documents with his own signature on the informed consent forms. Dr. McLeod also failed to perform required clinical lab tests for patients enrolled at his study site; failed to perform lab tests as required by study procedures and protocols; failed to accurately document and track which patients were or were not dispensed medication; and failed to report, track, and document when and/or whether any patients suffered or experienced adverse events while enrolled at his study site. The false and inaccurate data obtained by Dr. McLeod's study site was reported to the FDA as true and accurate data and was relied upon by the FDA in providing approval for Defendants' manufacture and sale of Ketek® in the U.S.

52. Relator is informed and believes that the FDA's investigation into Dr. William G. Terpstra's Study 3014 site discovered more than 20 violations of the study instructions. Relator is informed and believes that the FDA is evaluating or has evaluated Dr. Terpstra's conduct as a study site investigator. The results of this investigation are currently unknown to Relator. An FDA inspection of the Terpstra site found that Dr. Terpstra failed to follow the study plan and consistently failed to report adverse drug reactions. Relator is informed and believes that, as a result of the foregoing conduct, the data results from Dr. Terpstra's study site were inaccurate and false, but were nevertheless reported to and relied upon by the FDA in granting approval for Defendants' manufacture and sale of Ketek® in the U.S.

**4. Defendants Submit False Data to AIDAC**

53. On or about January 8, 2003, voting members of the AIDAC met to further consider FDA approval of Ketek® for marketing and sale in the United States.

54. During the January 8, 2003 meeting, Defendants concealed from the AIDAC the true and accurate information regarding the protocol violations that occurred with regard to Study 3014, and misrepresented that the data and study results submitted by Defendants and their physician study investigators were true and accurate, when in fact these representations were false. Defendants concealed from the members of the AIDAC the true facts regarding the false and inaccurate results of Study 3014, and misrepresented that the submitted results were true and accurate for the purpose of obtaining approval for the manufacture, marketing, and sale of Ketek® in the U.S.

55. Ketek® was approved for sale in Japan in 2003.

56. The AIDAC recommended FDA approval for the marketing and sale of Ketek® in the United States in January 2003.

57. The FDA sent an "approvable letter" to Defendants on January 24, 2003 for the marketing and sale of Ketek® in the U.S. The FDA approvable letter also requested documents regarding Study 3014 and post-marketing safety data relating to foreign sales of Ketek®.

58. Members of the AIDAC, upon learning the true facts and information regarding Defendants' concealment of true facts and fraudulent misrepresentations regarding the results of Study 3014 and the risks of serious harm resulting from the use of Ketek®, stated that they would not have recommended approval of the marketing and sale of Ketek® in the U.S. had they known the true facts and information concealed by Defendants regarding the risk of harm

associated with the use of Ketek®.

**5. Criminal Indictment of Study Investigator Dr. Kirkman-Campbell for Study 3014**

59. On or about August 29, 2003, Dr. Kirkman-Campbell, the lead investigator in Study 3014, was criminally indicated on 21 counts and accusations of fraudulent and criminal conduct regarding her actions and conduct in relation to Study 3014. Dr. Kirkman-Campbell pled guilty to one count and was sentenced to 57 months in prison.

60. The U.S. Department of Health and Human Services Division of Scientific Investigations ("DSI") issued a Memorandum on or about March 25, 2004 stating that the "monitoring program for study 3014 uniformly failed to detect data integrity problems when they clearly existed." The DSI Memorandum further stated that "the integrity of data from all sites involved in study 3014 cannot be assured with any degree of confidence."

**6. Ketek® Approved for Sale in U.S.**

61. On or about April 2, 2004, the FDA approved Ketek® for marketing and sale in the United States specifically for treatment of acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and community-acquired pneumonia.

62. Defendants thereafter engaged in a campaign of over-promoting Ketek® in written marketing literature, in written product packaging, and in direct-to-consumer advertising via written and television advertisements. Defendants' over-promotion of Ketek® was undertaken by promoting the safety and efficacy of the product, while concealing, misrepresenting, and actively downplaying the serious, severe, and life-threatening risks of harm to its users when compared with comparable or superior alternative drug therapies.

63. Prior to the FDA's approval of Ketek®, Defendants funded and undertook studies for the specific purpose of testing and determining the effect of Ketek® on humans during Phase III clinical trials. These studies demonstrated that Ketek® caused and/or was a significant contributing factor in cases of blurred vision, hepatic injury, and other dangerous health effects arising from the use of the product. Defendants concealed and misrepresented this information prior and subsequent to the FDA's approval of Ketek®.

64. Defendants knew that patients who used Ketek® during pre-clinical and clinical studies suffered adverse effects on the liver known as hepatotoxicity, and knew from the toxicology review of NDA 21-144 that use of Ketek® causes a greater risk and incidence of hepatoxicity than other comparable macrolide antibiotics.

65. Defendants also were aware that the results of the comparative Phase III clinical trials specifically examined the nature and extent of the effect of Ketek® on human patients and that the clinical trials demonstrated a greater proportion of patients with elevated transaminase levels who were treated with Ketek®, as compared to patients treated with other comparable antibiotics.

66. Defendants knew in January 2003, over a year before the FDA's approval of Ketek®, of at least 54 adverse events of hepatotoxicity associated with the use of Ketek® outside the United States. Defendants knew that 19 of these adverse events were of a "serious" and/or life-threatening nature.

67. In 2004, recognizing the increased risk and incidence of hepatotoxicity related to the use of Ketek®, the primary safety reviewer of NDA 21-144 expressed serious safety and risk/benefit concerns, and stated that:

> It is doubtful that approval could be granted for the indications of [acute bacterial sinusitis] or [acute bacterial exacerbation of chronic bronchitis], given the hepatic and visual risk profile of [Ketek®], the non-life-threatening nature of these infections, and the commercial availability of multiple alternative agents.

Ketek®, NDA 21-144, Medical Safety Team Leader Memorandum, Original Draft.

68. The Medical Team Leader on the second review of NDA 21-144, stated as follows:

> In the original NDA, a serious hepatic adverse event occurred in a [Ketek®]-treated patient with a liver biopsy showing centrilobular necrosis and eosinophilic infiltration, changes strongly suggestive of a hypersensitivity type drug-related liver injury and similar to those described in cases of trovafloxacin-associated hepatitis. Several months later, this patient went on to have an episode of asymptomatic elevations in his ALT and AST and a second liver biopsy showing changes consistent with chronic hepatitis, probably autoimmune, a finding consistent with neoantigen exposure after drug-related injury.

69. The Medical Safety Team Leader also expressed doubts regarding the accuracy of the information and data submitted by Manufacturer Defendants regarding the safety and efficacy of Ketek®, as follows:

> It is not clear from the data provided by the Applicant that either the quantitative or qualitative descriptions of post-marketing adverse events represented all data in the possession of the company.

70. Defendants aggressively marketed Ketek® after FDA approval and continued to fail to disclose their knowledge of the true risks of harm to human health and safety associated with this drug.

**B. <u>Relator Jamie Erfle's Experience With Off-Label Marketing of Ketek®</u>**

71. Relator Jamie Erfle worked as a field sales representative, or "detailer," for Sanofi-Aventis from June 2004 through April 2006. Her primary responsibility was to visit physicians, including internists and primary care physicians, in central New Jersey (Freehold

District) and persuade them to prescribe Ketek® to their patients.

72. During her course of employment, and with the implicit approval of her superiors, Relator became a participant to Sanofi-Aventis's aggressive strategy of marketing Ketek® for "off-label" uses, *i.e.* uses other than those for which the FDA approved the drug. These off-label uses for which Relator was asked to and did promote Ketek® to physicians included for treatment of otitis media, strep throat, and in particular for treatment of lyme disease.

73. The central region of New Jersey was considered to have a high concentration of persons with lyme disease, and for this reason was designated by Defendants as a target sales territory.

74. Within this region, two physicians, Dr. Steven Streit and Dr. Elaina Eisner, who were world-renowned as lyme-tick disease specialists and whose practices consisted primarily of treating patients suffering from this condition, were targeted for particularly intense off-label promotional activity.

75. With the approval of her supervisor, Alan Chant, and Mr. Chant's supervisor, Jay Rush, Relator made numerous office visits to these two physicians during which she marketed Ketek® for the off-label use of treating lyme tick disease.

76. On many visits to these two physicians, Mr. Chant and Mr. Rush accompanied Relator, but chose to remain in the car in order to maintain plausible deniability as to the off-label marketing that occurred in the doctors' offices. On visits to other doctors where no off-label promotion as occurring, Mr. Chant and Mr. Rush typically would accompany Relator into the doctor's office.

77. Mr. Chant and Mr. Rush knew that Relator was urging doctors to prescribe

Ketek® for treatment of lyme disease, but made comments to her that "I did not hear that" or "I did not see that" when advised as to the conversations that took place in the doctors' offices.

78. Relator's marketing was spectacularly successful, vaulting her and other members of her team into the top ten percent in Ketek® sales volume throughout the United States on numerous occasions.

79. During her employment with Sanofi-Aventis, Relator knew of other sales agents who also engaged in off-label marketing of Ketek® for treatment of lyme disease. This practice of off-label marketing was known among sales representatives as "priming the pump."

80. During her employment with Sanofi-Aventis, Relator and other sales agents were approved and encouraged by their supervisors to promote off-label uses for Ketek®. Supervisors and Sanofi-Aventis officials encouraged sales representatives to advise physicians to "rest assured that Ketek works for the same bacterial strands that cause infections in other part of the body," for which Ketek was not approved, and that "other doctors are using it for infections in other parts of the body" than those for which the FDA had approved the drug's use.

## COUNT I

## VIOLATION OF THE FALSE CLAIMS ACT, 31 U.S.C. § 3729

81. Relator repeats and realleges paragraphs 1-80 of this Complaint in their entirety.

82. From at least June 2004 through April 2006, Defendants knowingly, with reckless disregard, or with deliberate ignorance of the truth or falsity of the information involved conspired with physicians and pharmacies to defraud the United States Government by causing false or fraudulent claims to be paid or approved by the Government in violation of 31 U.S.C. § 3729(a)(3).

83. From at least June 2004 through April 2006, Defendants knowingly, with reckless disregard, or with deliberate ignorance of the truth or falsity of the information involved conspired with doctors and pharmacies to cause to be presented to various state and federally-funded Medicaid health care programs false or fraudulent claims for payment in violation of 31 U.S.C. § 3729(a)(3).

84. The United States, its fiscal intermediaries and state Medicaid programs were unaware of Defendants' conspiracies or the falsity of the records, statements and claims made by Defendants' co-conspirators and as a result thereby have paid and continue to pay Medicare, Medicaid and CHAMPUS reimbursement that they would not otherwise have paid.

85. The United States and the State Medicaid Programs have been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

a. that, by reason of the aforementioned violations of the False Claims Act, this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages that the United States has sustained because of Defendants' and the co-conspirators' actions, plus a civil penalty of not less than $5,000 nor more than $10,000 for each violation of 31 U.S.C. § 3729;

b. that Relator, as a *qui tam* Plaintiff, be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act and/or any other applicable provision of law;

c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. that Plaintiffs and Relator have such other and further relief as this Court deems just and proper.

**COUNT II**

**VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT, N.J.S.A. 2A:32C-1 TO 17**

86. Relator repeats and realleges paragraphs 1-85 of this Complaint in their entirety.

87. From at least June 2004 through April 2006, Defendants knowingly, in reckless disregard, or with deliberate ignorance of the truth or falsity of the information involved conspired with physicians and pharmacies to defraud the State of New Jersey by causing false or fraudulent claims to be paid or approved by the State of New Jersey in violation of N.J.S.A. 2A:32C-3.

88. From at least June 2004 through April 2006, Defendants knowingly, in reckless disregard, or with deliberate ignorance of the truth or falsity of the information involved conspired with doctors and pharmacies to cause to be presented to New Jersey's State-funded Medicaid health care program false or fraudulent claims for payment in violation of N.J.S.A. 2A:32C-3.

89. New Jersey's State Medicaid program was unaware of Defendants' conspiracies or the falsity of the records, statements and claims made by Defendants' co-conspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that it would not otherwise have paid.

90. The New Jersey State Medicaid program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

a. that, by reason of the aforementioned violations of the New Jersey Flase Claims Act, this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two time and not more than three times the amount of damages that New Jersey has sustained because of Defendants' and the co-conspirators' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of N.J.S.A. 2A:32C-3;

b. that Relator, as a *qui tam* plaintiff, be awarded the maximum amount allowed pursuant to N.J.S.A. 2A:32C-7 and/or any other applicable provision of law;

c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and

d. that Plaintiffs and Relator be awarded such other and further relief as this Court deems just and proper.

Dated: 1/24, 2011

Respectfully submitted,

WILLIAMS CUKER BEREZOFSKY, LLC

Gerald J. Williams, Esquire
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